DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Orthoclone OKT*3
Docket No. 86E-0357

NOV 14 1986

The Honorable Donald J. Quigg
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Commissioner Quigg:

This is in regard to the application for patent extension for U.S. Patent No. 4,361,549, filed by Ortho Pharmaceutical Corporation, under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Orthoclone OKT*3, the human drug product claimed by the patent.

The total length of the review period for Orthoclone OKT*3 is 2,301 days. Of this time, 1,488 days occurred during the testing phase and 813 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 3, 1980.

   The applicant states that the investigational exemption (IND) time for the drug product is inapplicable. However, FDA records indicate that an IND for the product became effective on March 3, 1980.

2. The date the product license application was initially submitted with respect to the human drug product under subsection 351 of the Public Health Service Act: March 29, 1984.

   FDA has verified that the product license application for the drug product was filed on March 29, 1984.

3. The date the application was approved: June 19, 1986.

   FDA has verified that product license 996 for the drug product was approved on June 19, 1986.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Geoffrey G. Dellenbaugh, Esq.
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